In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 12-77V

(to be published)

AUDREY MORGAN, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Filed: December 6, 2017 Decision Denying Entitlement; Tetanus-Diphtheria-Acellular Pertussis ("Tdap") Vaccine; Varicella Vaccine; Hepatitis A Vaccine; Meningococcal Vaccine; Gastroparesis.

F. John Caldwell, Jr., Maglio Christopher & Toale, PC, Washington, D.C., for Petitioner.

Ann Martin, U.S. Dep't of Justice, Washington, D.C., for Respondent.

DECISION DENYING ENTITLEMENT[1]

Audrey Morgan[2] filed this petition in February 2012, alleging that she developed gastroparesis (a condition characterized by delayed stomach emptying, thereby interfering with digestion) and abdominal migraines as a result of her April 2009 receipt of the tetanus-diphtheria-acellular-pertussis ("Tdap"), Varicella, Hepatitis A, and meningococcal vaccines. Pet. at 1. An entitlement hearing was held in Washington, DC, on April 24, 2017, and May 3, 2017. After considering the record as a whole, and for the reasons explained below, I find that Petitioner has

[1] Because this Decision has been designated for publication, it will be posted on the United States Court of Federal Claims' website, and in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to a published decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available in its current form. *Id.*

[2] The Petition was originally filed by Michael and Karen Morgan (Petitioner's parents) due to her status as a minor, and identified her by initials. After Ms. Morgan became 18, the Petition was amended on August 22, 2014 (ECF No. 51), to state her full name.

not met her burden of proof, and therefore is not entitled to a damages award. Petitioner has not offered a reliable medical/scientific theory connecting the pathogenesis of her gastroparesis to her vaccinations, and has not shown that her circumstances reflect the theory in action.

I. Factual Background

Vaccination and Alleged Initial Symptoms

As the medical record reveals, before receiving the vaccines at issue Ms. Morgan was a relatively healthy 12-year-old, with no relevant significant health issues beyond some chiropractic treatment she had previously received for back pain. Ex. 4 at 7. However, there are some records regarding pre-vaccination medical treatment bearing on the claim. Thus, on February 9, 2009, Ms. Morgan saw her pediatrician at Haddonfield Pediatrics ("Haddonfield") in Haddonfield, New Jersey, who noted that she was recovering from a week-long flu-like illness presumed to be viral because she presented at the visit with a yellow tongue. *Id*.

On April 9, 2009, Haddonfield called Petitioner's father, Mr. Michael Morgan, to schedule a check-up appointment for Ms. Morgan, for the purpose of reviewing the results of her February chiropractic treatment with her pediatrician. Ex. 4 at 7. About two weeks later, on April 15, 2009, Ms. Morgan received the four named vaccines at her pediatrician's office. Ms. Morgan otherwise underwent a general physical at the time, with her treater noting that she was a "well 12 ¾ yo" with no significant complaints. *Id*.

As noted in more detail below, Petitioner and other fact witnesses allege that she experienced a vaccine reaction very shortly after, and that these symptoms progressed over the next three to four months, to a point where they could not be ignored. The medical record, however, does not completely corroborate this narrative. Thus, Ms. Morgan's next doctor's visit after her April 2009 vaccinations occurred on July 13, 2009 (around three months later). Ex. 4 at 8. At that time, she reported experiencing nausea that had existed since March 2009 (*before* the relevant vaccines), but had worsened to the point that she had felt nauseated "non-stop" for the prior five days. *Id*. The blood work, chest x-ray, and thyroid studies performed were all unremarkable. *Id*. at 58-62. Petitioner returned to her treater three days later (on July 16, 2009), reporting diarrhea that morning, and that her nausea was off and on. *Id*. at 8. Her treater made a notation that Ms. Morgan was wearing a wristband for morning sickness, but that otherwise she was "smiley and in no distress." *Id.* She was diagnosed with gastroesophageal reflux disease ("GERD") and prescribed Prilosec. *Id*.

Increase in Symptom Severity

Ten days later, on July 26, 2009, Mr. Morgan called the pediatrician stating that in addition to the previously-reported nausea, Ms. Morgan was now "feeling off" and was off-balanced, seeing black when she stood. Ex. 4 at 9. The Morgans were directed to take Ms. Morgan to the emergency

room at St. Christopher's Hospital for Children, in Philadelphia, Pennsylvania. *Id*. This visit, and the visits thereafter to the hospital, included extensive testing, most of which resulted in normal findings (except for a finding of a sustained increase of eosinophils, which can be associated with an allergic response).[3] *Id*. at 60.

Between August and mid-October 2009, Ms. Morgan continued to undergo evaluation, with most of the focus on exploring whether there was a psychological explanation for her symptoms. Ex. 4 at 49. Her nausea was noted to be triggered by smell, sounds, light, and car travel. Ex. 20 at 16. The testing during this period did not, however, illuminate any evidence of an ongoing inflammatory or viral process, or any other concerning issues. Thus, Petitioner underwent an ultrasound scan of her abdomen in August that produced no evidence of abnormality. *Id.* at 57. Later, she received a CT brain scan on September 8, 2009, which was deemed unremarkable. *Id.* at 51. An esophagogastroduodenoscopy[4] performed in mid-August similarly was read as normal. Ex. 7-1 at 43.

Ultimately, Ms. Morgan's various physicians were unable to make a definitive diagnosis for her condition, leading her to be referred to Dr. Cuckoo Choudhary, a gastroenterologist at Thomas Jefferson Hospital in Philadelphia, Pennsylvania. *See generally* Ex. 5. Dr. Choudhary saw Petitioner in the first half of October, and performed additional testing, including tests for celiac disease, hepatic function, and a CT scan of the abdomen, all of which produced normal results. *Id*. at 9-16. Dr. Choudhary also ordered a scintigraphy test designed to evaluate the time it took for gastric emptying. The results of that test, performed on October 12, 2009, revealed that Ms. Morgan had a measurable, although not extreme, delay in emptying - her gastric emptying half-time was 148 minutes, versus a normal rate of 90-120 minutes. *Id*. at 17-18. Based upon this test result, Ms. Morgan was subsequently diagnosed with gastroparesis.[5] *Id*. at 23.

Subsequent Treatment

Ms. Morgan was prescribed a variety of medications to help with her GI symptoms, the most effective of which proved to be erythromycin[6] when taken prior to eating. Ex. 6 at 6. In

[3] In his testimony, Respondent's expert, Dr. Randy Longman, endeavored to explain the significance of these eosinophils readings, suggesting that they potentially hinted at an alternative explanation for her gastroparesis. Tr. at 328-29. Ultimately, however, although such readings could have shed light on a possible cause for Ms. Morgan's gastroparesis, her treaters did not pursue further testing relevant to these findings, thereby diminishing their value herein as explanatory. *Id.* at 329-30.

[4] An esophagogastroduodenoscopy is an endoscopic exam of the esophagus, stomach, and duodenum. *Dorland's Illustrated Medical Dictionary* 648 (32nd ed. 2012) (hereinafter "*Dorland's*").

[5] This record notes that Ms. Morgan likely had gastroparesis, although it is unclear from the record if this was the date of her official diagnosis. The records also do not make it apparent which doctor made the diagnosis and when that visit was conducted. However, records after this date reference gastroparesis as Petitioner's diagnosis.

[6] Erythromycin is a broad spectrum antibiotic used to treat a variety of bacteria. *Dorland's* at 645. Ms. Morgan was also prescribed Klonopin and Zoloft for anxiety, as well as several medications for the migraine headaches she was

addition, on December 30, 2009, Ms. Morgan underwent another esophagogastroduodenoscopy revealing that her esophagus and duodenum were normal, and her stomach had a small amount of residual fluid. Ex. 5 at 23. While under anesthesia, Ms. Morgan had botox injections in her stomach.[7] *Id*. The botox proved to be helpful, and it is now an ongoing element of her continued treatment. *Id*. at 22.

By the spring of 2010, Ms. Morgan was exhibiting some improvement. During an April 2010 visit with Dr. Ritu Verma at the Children's Hospital of Philadelphia, it was noted in the record that "[s]ince the botox injection, Audrey reports that her abdominal pain and headaches have essentially resolved, although she still feels nauseated on a daily basis . . . the severity of her nausea has [otherwise] greatly improved." Ex. 6 at 13. At this visit, Ms. Morgan underwent a repeat gastric emptying study, which no longer revealed abnormal results. *Id*. at 19.

Dr. Verma opined as to several potential etiologies for Ms. Morgan's persistent nausea, including "gastroparesis, infectious, anatomic, reflux, allergic, migraine, lactose intolerance, small bowel bacterial overgrowth, or neurologic." Ex. 6 at 14. Like other treaters, however, Dr. Verma was unable to pinpoint a primary cause, given that all of Ms. Morgan's other testing (with the exception of the gastric emptying scintigraphy) had returned normal results. She did conclude that erythromycin was contributing to her improving symptom of nausea, because when Ms. Morgan ceased that medication, her nausea worsened, while her gastric emptying remained within the normal range. *Id*. at 5. Rather than a diagnosis of gastroparesis, Dr. Verma labelled Ms. Morgan's condition as "nausea alone" beginning in June 2010 and restarted the erythromycin. *Id*. at 9.

The Morgans continued thereafter to seek treatment for Petitioner. In August 2011, the Morgans began to track Petitioner's symptoms on a calendar at the request of Dr. Olga Katz at Advanced Neurology Associates in Philadelphia, Pennsylvania. Ex. 3 at 8-9. In addition to daily nausea, the entries noted varying symptoms including hot flashes, chills, dry throat, difficulty swallowing, and loss of vision. *Id*. Ms. Morgan remained under the care of Dr. Katz, who wrote letters to Ms. Morgan's school indicating that home-bound schooling was appropriate, and stating that Ms. Morgan's diagnoses included syringomyelia, transformed migraine, chronic migraine, and autonomic dysregulation.[8] Ex. 12 at 8.

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experiencing. Ex. 20 at 17. Ms. Morgan did not receive any treatments, such as plasmapheresis, which would indicate that her doctors suspected an autoimmune condition was at play.

[7] Botox is a paralytic agent that, when used in the context of gastroparesis, helps relax the sphincter muscle at the end of the stomach, allowing food to pass more easily into the upper intestine. Tr. at 232.

[8] Syringomyelia is a slowly progressive syndrome of cavitation in the central segments of the spinal cord, and results in neurologic deficits—usually muscular weakness and atrophy. *Dorland's* at 1858. Autonomic dysregulation is self-controlling dysregulation. *Id*. at 182.

As is described in more detail below, Ms. Morgan now reports that she continues to feel nausea frequently but is able to manage going to school—on an adjusted schedule—as well as participate in some limited athletic activities. Tr. at 3.

II. Hearing Testimony

A. *Fact Witnesses*

1. Ms. Morgan

Ms. Morgan began her testimony by describing her activities as a teenager. Tr. at 7. Specifically, she discussed the intensive training she participated in as an Irish step dancer, which included practice six nights a week during competition season (from about January to May). *Id*. She also ran track at her school. *Id*. at 9. Today, however, Ms. Morgan testified, she is unable to take part in such activities because of her condition. *Id*. at 8.

Regarding her vaccination, Ms. Morgan recalled that the pediatric appointment was made with her primary care physician because she needed a routine physical, but had not required a pediatric visit for other conditions that year (with the exception of the February 2009 visit to treat her URI). Tr. at 8. The appointment was on April 15, 2009, ten days before her 13th birthday. *Id*. at 9. Ms. Morgan reported that she went to the visit with her mom and received four vaccines. *Id*. at 8.

Much of Ms. Morgan's testimony (similar to that provided by her parents) was otherwise aimed at establishing an onset of symptoms close in time to, but after, the April 2009 vaccinations. Thus, she recalled that the weekend after receiving the vaccinations, she was running at a track meet. Immediately after finishing her mile race she began dry heaving. Tr. at 9. The next day, Ms. Morgan competed in an Irish step dance competition and found herself feeling very nauseated after every dance. *Id*. Although there were some records that suggested her GI symptoms had begun in March, Ms. Morgan maintained in her testimony that "any fatigue she was experiencing was just from the weeks—from all the shows. Those two weeks of like—St. Patrick's Day." *Id.* at 16.

Ms. Morgan reported that her condition continued to deteriorate in the weeks and months following vaccination. Tr. at 10. This deterioration occurred in the midst of her Irish step dance competition schedule, eventually resulting in her being forced to stop dancing entirely. *Id*. She also began to have trouble waking up, and spent more time home-bound, because the heat of summer made her nausea worse. *Id*. Petitioner travelled to Florida in early July 2009 to visit her extended family, and recalled that she was fine during the trip until the return home, when she had to lie on the ground at the airport due to her discomfort, making her family think she had a stomach bug. *Id*.

Despite the symptoms she was experiencing, Ms. Morgan did not see a doctor, because she and her family attributed the problems she was having as related to the beginning of menstruation or some other benign physical growth development problem. Tr. at 11. The turning point that led the Morgans to seek treatment for Petitioner's GI symptoms came, however, when she attended a swim meet on July 11, 2009 but did not feel well enough to get in the pool. *Id*. In addition, sometime in July 2009 (three months after vaccination), Petitioner started to withdraw from social gatherings, was noticeably less happy, and sometimes would not leave her bed. *Id*. at 12. Although the medical record establishes that Petitioner visited the doctor in mid-July for complaints of persistent nausea since March 2009, in her testimony Petitioner could not recall the details of what she told the doctors about onset at that visit. Tr. at 20-21.

Ms. Morgan otherwise testified about her gastroparesis diagnosis as well as subsequent symptoms and treatment. Tr. at 12-13. In addition to the severe nausea, she began experiencing both abdominal and head migraines, as well as esophageal sensitivity, making it difficult for her to attend her college classes. *Id.* Today, while Ms. Morgan is able to attend school and participate in some athletic activities, such as hang-gliding, she has modified her clothing choices as well as her school schedule to accommodate her continued nausea and the side effects of her medication. *Id*. at 13.

2. Mr. Michael Morgan

Mr. Morgan, Petitioner's father, gave testimony that for the most part was intended to identify onset of her symptoms. He testified to being very involved with all of his children's extracurricular activities. Tr. at 35. In particular, his three daughters were all very successful Irish step dancers (a central activity for the entire Morgan family), competing for world championships all over the Northeastern United States. *Id*. at 35-36. To help keep track of all the different competitions for his daughters, Mr. Morgan kept meticulous notes in a spreadsheet with all the details of the competitions, including dates. *Id.* at 44. His notes state how the competition organized the age groups, as well as the commentary from the judges, and some of his observations of how performances went. *Id*.; *see also* Exs. 81 (ECF No. 80). Mr. Morgan also submitted a personal electronic calendar he had prepared beginning in the spring of 2009 that tracked Petitioner's symptoms. Exs. 80, 82-84 (ECF No. 80).[9]

As Mr. Morgan explained, the busiest season for Irish step dancing is in March around Saint Patrick's Day. Tr. at 38. He therefore professed to have good recall of Petitioner's physical wellness in March 2009. Around that time period, he testified, he received a call from the

[9] On cross-examination, Mr. Morgan attempted to clarify when precisely he had begun recording his impressions of Ms. Morgan's symptoms. Tr. at 72-73. Thus, he acknowledged that notes of symptoms beginning in April 2009 were created in August 2009, after Dr. Choudhary requested that he track Ms. Morgan's symptoms, but in so doing included the earlier symptoms he recalled. *Id.* at 72. By contrast, he testified that he created his dance competition notes contemporaneously with events. *Id*. at 72.

pediatrician's office instructing him to bring in Ms. Morgan for a well-child exam, as she had not had any recent need for medical attention. *Id.* at 40. Indeed, despite the busy dance schedule that March, the only health issue he could recall her experiencing involved a minor injury to her toe and hamstring. *Id*. Mr. Morgan's dance calendar/diary largely confirmed this recollection. Ex. 81. One note, however, from before vaccination on March 21, 2009, stated "no stamina," but attributed it to "too many shows this week." *Id*. at 1.

Mr. Morgan's calendar of Petitioner's nausea symptoms recorded their first appearance three days after vaccination, on April 18, 2009, when she got sick at her track meet. Ex. 83 at 2. Every weekend after that through the end of the year, she had some sort of difficulty with nausea, although she seemed to be tolerating her dance classes during the week better. *Id*. at 3-4. From May 9, 2009 through November 2009, there were only two instances Mr. Morgan recalled when Petitioner felt well enough to dance. Ex. 81 at 1. His personal calendar also denotes some dates in May 2009 (1st and 20th) as "sick," although it is unclear from the calendar who in the family was sick. Ex. 80 at 3.

However, as summer progressed, Mr. Morgan testified, Petitioner's occasions of nausea became more frequent. Tr. at 50-54. After returning from the family trip to Florida in July 2009 referenced in Petitioner's testimony, Mr. Morgan recalled that Petitioner's symptoms became so severe that he and his wife opted to bring Ms. Morgan to the doctor in the middle of July. *Id*. Her symptoms persisted thereafter, subsequently impacting her ability to participate in field hockey camp and a summer camp. *Id*. at 50-51. Due to the increasing severity and impact of the symptoms, Mr. Morgan took Ms. Morgan for further testing. *Id*. at 52-53. By the fall, Ms. Morgan received the gastroparesis diagnosis.

There were some discrepancies between statements Mr. Morgan previously made about Petitioner's onset and his trial testimony (supplemented by the diary and calendar filed in this case after the hearing had concluded). Thus, Mr. Morgan acknowledged that the affidavit filed in the case stated he did not remember Petitioner being sick after her dance competition in April, but upon "refreshing his recollection" with his wife and Petitioner's affidavits he recalled that Petitioner had in fact been nauseated after that competition. Tr. at 73; Ex. 78 at 1. In response to questions about a March 2009 pre-vaccination onset suggested by certain records, Mr. Morgan proposed that such references were likely the product of imprecision in recounting to treaters the length of Petitioner's symptoms as having lasted for a "couple of months," adding that (without the benefit of review of the calendars and diaries Mr. Morgan had relied upon) it was difficult during that time to pinpoint the exact onset of her condition. *Id*. at 81.

3. Mrs. Karen Morgan

Mrs. Morgan's testimony was consistent with the statements of her husband and daughter. She noted that Ms. Morgan was the most athletic and healthy of her three children, having no major illnesses prior to vaccination. Tr. at 90. Mrs. Morgan also reiterated that March for her family was very busy because of Saint Patrick's Day and the popularity of Irish step dance performances during that time. *Id*. at 92. She recalled taking Petitioner to her April 2009 well-child visit where she received her vaccines, and that three days later Petitioner had issues with nausea following a track meet. *Id*. at 97.

Mrs. Morgan's concern about Petitioner's condition began to grow as she saw the impact of the symptoms on Ms. Morgan's activities, leading the Morgans to take Petitioner to the doctor after the July 2009 family trip to Florida. Tr. at 100. Specifically, Mrs. Morgan remembered the symptoms in July as a "very pronounced change" from those earlier in the spring. *Id*. She noted that by this point Petitioner was having difficulty getting out of bed, and thus was not simply having trouble with her stamina after dancing or athletic endeavors. *Id*.

Like her husband, Mrs. Morgan was asked about discrepancies between her recollection of onset as having occurred close in time to the vaccinations and records suggesting an earlier, pre-vaccination onset. Mrs. Morgan conceded that either she or Petitioner could have relayed to the doctor in July 2009 that the symptoms began in March, rather than April as she was now claiming. *Id.* at 110. She also reiterated the view of her husband that it was difficult to pinpoint a specific onset date, remembering that she was only informing treaters in general terms that the symptoms had begun that spring or a "couple of months ago." *Id.*

B. *Petitioner's First Expert – Dr. Eric Gershwin*

Dr. Gershwin is an immunologist who testified on behalf of Petitioner and offered a single expert report in the case. Tr. 117-56, 356-65; Ex. 42, dated Sept. 30, 2015 (ECF No. 59-1) ("Gershwin Rep."). Dr. Gershwin opined that Ms. Morgan's April 2009 vaccinations caused her gastroparesis. Gershwin Rep. at 5.

Dr. Gershwin received his bachelor's degree from Syracuse University in Syracuse, New York, followed by his medical degree, which was completed at Stanford University in Stanford, California. Ex. 43, dated Sept. 30, 2015 (ECF No. 59-2) ("Gershwin CV"). He then completed his internship and residency at Tufts-New England Medical Center in Boston, Massachusetts. *Id*. at 2. After completing a fellowship in immunology with the National Institutes of Health, Dr. Gershwin became an assistant Professor in Rheumatology and allergy at the University of California, School of Medicine in Davis, California. *Id*. at 2, Tr. at 121. Along with maintaining a clinical practice, Dr. Gershwin remains employed by the University of California, School of Medicine in Davis, California as the Chief of the Division of Rheumatology/Allergy and Clinical Immunology.

Gershwin CV at 1-2; Tr. at 120. He currently serves as the editor-in-chief of the Journal of Autoimmunity as well as several other publications focusing on autoimmunity. Tr. at 121. Although Dr. Gershwin was recognized at hearing as an expert in immunology, he acknowledged that he is not a gastroenterologist, and he thus relied entirely on Petitioner's other expert, Dr. John Santoro, for opinions specifically relevant to gastroparesis, as he has not worked with that disorder at all. *Id*. at 129, 134-35.

To begin his testimony, Dr. Gershwin described the nature of autoimmune conditions and autoimmunity. He defined it as occurring when a person's immune system reacts to its own tissues in the body. Tr. at 123. Although genetics can play a role in autoimmunity, outside/environmental events usually initiate an autoimmune process. *Id*. at 124. One specific mechanism Dr. Gershwin proposed as responsible for autoimmunity and (in his opinion) applicable to this case is molecular mimicry. *Id*. As he described it, molecular mimicry occurs when a person's body is exposed to something in the environment (vaccination or infection) and in the process of reacting to it, autoantibodies created by the body cross-react with an antigen contained in the body instead of the foreign antigen found in the vaccine or infection, because of a mimicking resemblance between the presenting antigen and self-protein sequences/structures. *Id*.[10] However, Dr. Gershwin noted that autoantibodies are not always detected relating to known autoimmune disorders, and that specific autoantibodies relevant to a particular illness may often remain unidentified. *Id*. at 125-26. Autoimmune conditions are very diverse, and thus do not always have systemic markers, especially when an autoimmune condition is known to be organ-specific. *Id*. at 130. In such instances, patients may have manifestations of an autoimmune condition only in the target tissue of the effected organ—here, for example, the stomach. *Id*.

Dr. Gershwin categorized Ms. Morgan's illness, gastroparesis, as an enteric neuropathy, produced by either an inflammatory or immunological insult to the autonomic nervous system[11] understood to control the GI tract. Gershwin Rep. at 3; Tr. at 143 (describing gastroparesis as "something neurologic within the GI tract"). He described three diseases that have classically been associated with enteric neuropathies such as gastroparesis—paraneoplasia, infectious diseases (such as Chagas disease[12]), or primary central nervous system disorders. Gershwin Rep. at 3. In each, inflammatory infiltrates responsible for neurologic dysfunction have been found in biopsied

[10] The concept of molecular mimicry is common to Vaccine Program cases, and I have ruled on its applicability to a claimant's causation theory numerous times. *See, e.g., Al-Uffi v. Sec'y of Health & Human Servs.,* No. 13-956, 2017 WL 1713113 (Fed. Cl. Spec. Mstr. Feb. 22, 2017); *Lozano v. Sec'y of Health & Human Servs.,* No. 15-369, 2017 WL 3811124 (Fed. Cl. Spec. Mstr. Aug. 4, 2017).

[11] The autonomic nervous system is dedicated to the regulation of the activity of the cardiac muscle, smooth muscle, and glandular epithelium. *Dorland's* at 1859.

[12] Chagas disease is a condition that can be preceded by a nodule at the site of an inoculation, high fever, or swelling of the face, and results in gastrointestinal manifestations in the esophagus and megacolon. *Dorland's* at 530.

tissue, and Dr. Gershwin deemed it likely that anti-neuronal antibodies mediate the pathologic process. *Id*. In this case, however, there was no evidence in the medical records of the discovery of antibodies associated with an autoimmune process. Dr. Gershwin acknowledged this, although he attributed the evidentiary omission to the fact that Ms. Morgan's treaters would not have understood her ambiguous symptoms to suggest the presence of an autoimmune problem, and therefore did not look for possible autoantibodies. *Id.* at 147.

Here, Dr. Gershwin maintained that Ms. Morgan's gastroparesis was the result of an immunological insult—a vaccine—to the autonomic nervous system, occurring via molecular mimicry and producing an inflammatory response. Gershwin Rep. at 3; Tr. at 124. Cross-reactivity occurred, causing a loss in immune tolerance, which he proposed in turn caused T and B immune system cells[13] to be inappropriately activated, thereby damaging Ms. Morgan's GI system. Gershwin Rep. at 4. He lacked direct evidence (for example, in the form of literature linking vaccination with gastroparesis or similar GI illnesses) to establish this proposed disease process, but nevertheless maintained it was plausible, especially given the (a) lack of alternative environmental explanations, and (b) the close timing between vaccination and first onset of Ms. Morgan's symptoms. Tr. at 144, 146 (concluding that Petitioner's condition was autoimmune after "a process of elimination"). He also analogized the kind of autonomic neurologic injury that would negatively affect GI motility to Sjögren's syndrome, an autoimmune condition that can manifest with autonomic neuropathy. Gershwin Rep. at 3; *see also* K. Mori, et al., *The Wide Spectrum of Clinical Manifestations in Sjögren's Syndrome-Associated Neuropathy*, 128 Brain 2518-34, 2527 (2005), filed as Ex. 56 (ECF No. 60).[14]

To support his opinion that molecular mimicry was a plausible autoimmune mechanism for gastroparesis, Dr. Gershwin relied on Cusick, et al., *Molecular Mimicry as a Mechanism of Autoimmune Disease,* 41 Clinical Rev. Allergy Immunology 1, 102-11 (2012), filed as Ex. 76 (ECF No. 75) dated April 14, 2017 ("Cusick"). Cusick discussed molecular mimicry in the context of autoimmune diseases, noting that an autoimmune reaction could occur even where peptide sequence homology could not be demonstrated between an infectious agent or other antigen and a self-protein structure. Gershwin Rep. at 4; Cusick at 3-4. Moreover, the Cusick authors proposed that (for cases in which an initial cross-reaction mediated by molecular mimicry was understood or thought to be likely), the homology initiated by molecular mimicry causes self-reactive non-specific immune cells to be primed, creating a "fertile field" for additional inflammatory responses. Cusick at 4. Thereafter, a future environmental insult would induce the primed cells to cause an autoimmune condition. *Id*.

[13] T and B cells are the body's immunologically competent cells—T cells are responsible for cellular immunity, while B cells control humoral (blood) immunity. *Dorland's* at 1084.

[14] Neither this article, however, nor the other articles filed by Petitioner addressing Sjögren's syndrome involved the specific condition of gastroparesis, as opposed to other kinds of symptoms associated with autonomic neuropathic injuries, like syncope or orthostatic intolerance.

Dr. Gershwin admittedly could not identify a specific antigen that might have triggered the original proposed autoimmune process, given that Ms. Morgan received four vaccines in April 2009, but noted that gastroparesis was a rare condition, unstudied in animal models or by the pharmaceutical industry, and therefore this level of investigation into its mechanisms did not exist. Tr. at 139-40; Gershwin Rep. at 3. Dr. Gershwin did suggest, however, that in his view the most likely culprit was the meningococcal vaccine because Ms. Morgan had not received it previously (and therefore lacked immunologic "experience" with it), and because of its makeup of polysaccharides, which he proposed could cross-react with ganglioside antigens located in the intestines – specifically the gastric neurologic system, or a neuro-antigen within the stomach. Tr. at 139, 140-41, 144. Petitioner offered no direct evidence, however, in which this proposed mechanistic process had been established or tested.

With respect to whether Ms. Morgan possessed a genetic predisposition to an autoimmune disease, Dr. Gershwin was somewhat ambivalent. Thus, although her father has a demonstrated history of chronic inflammatory demyelinating polyneuropathy (an autoimmune condition),[15] Dr. Gershwin could not opine if this created a family susceptibility for Ms. Morgan as well. Tr. at 145. At the same time, he proposed that Ms. Morgan had to possess a "unique genetic repertoire," or she would not have experienced an autoimmune condition in the first place. *Id*. at 152. He could not provide more specific testimony regarding that repertoire, or what evidence established it (other than by pointing to the fact of Ms. Morgan's injury).

Dr. Gershwin (relying on Dr. Santoro's assertions specific to the course of gastroparesis and its clinical symptomology) also asserted that the timing of Petitioner's symptoms was medically acceptable. Ms. Morgan's dry heaving and nausea starting three days after vaccination, he maintained, was compatible with the time he would expect it to take for an autoimmune process sufficient to cause injury to occur. Tr. at 129. Dr. Gershwin stated that onset of vaccine-caused gastroparesis could occur any time between three days and four or five months. Gershwin Rep. at 3. In support, Dr. Gershwin emphasized Pande *et al.*, *Inflammatory Causes of Gastroparesis: Report of Five Cases*, 47 Digestive Disease and Sciences 12, 2664-68 (2002), filed as Ex. 45 (ECF No. 60) ("Pande"), a review article involving three post-vaccination case studies of gastroparesis. Tr. at 149.

Dr. Gershwin's testimony further attempted to address some of the criticisms raised by Respondent's expert about purported deficiencies in his theory. Thus, in response to the argument that Ms. Morgan's condition was unlikely autoimmune in nature because treaters never proposed classic treatments for autoimmune conditions (e.g. plasmapheresis), Dr. Gershwin argued that not

[15] In fact, Mr. Morgan brought his own vaccine claim in 2011 after receiving the influenza vaccine and subsequently developing chronic inflammatory demyelinating polyneuropathy. In 2015, I issued a Decision on damages in his favor, based on the stipulation filed by the parties. *Morgan v. Sec'y of Health & Human Servs.,* No. 11-103V, 2015 WL 465437 (Fed. Cl. Spec. Mstr. Jan. 9, 2015).

all autoimmune conditions (such as rheumatoid arthritis and myasthenia gravis) respond favorably to such treatments. Tr. at 126. In fact, plasmapheresis could fail if the body continued to produce more and more autoantibodies. *Id*. He also downplayed the lack of objective evidence of antibody markers, noting that most treaters would not have thought to look for them when Petitioner initially presented with persistent nausea in July 2009. *Id*. at 147, Gershwin Rep. at 3.

Dr. Gershwin similarly rejected Respondent's proposed alternative causes for Ms. Morgan's injury. He acknowledged that anxiety and depression can contribute to gastroparesis, but dismissed the idea that the record established any proof of anxiety *before* her gastroparesis diagnosis. Tr. at 137. Rather, to the extent (as Respondent demonstrated in cross-examination (*see, e.g.,* Tr. at 137)) that the medical record *did* contain proof that Petitioner had addressed issues relating to anxiety, Dr. Gershwin maintained that such records were from years after vaccination, and thus more likely reflected a *response* to her abdominal issues instead of cause. *Id*. He also questioned the proposal that Ms. Morgan's apparent pre-vaccination infection was a possible cause for her gastroparesis, deeming it too far removed from onset in April to be a plausible explanation. *Id.* at 148. While he allowed for the possibility that certain autoimmune conditions can have autoantibodies present many years before onset, he would usually expect an autoantibody-mediated process to occur more close in time to the event causing the autoimmune reaction. *Id*.

C. *Petitioner's Second Expert – Dr. John Santoro*

Petitioner's second expert was Dr. Santoro, a gastroenterologist. He testified at hearing and provided two expert reports. Ex. 31, dated Aug. 14, 2014 (ECF No. 47) ("Santoro Rep."); Ex. 41, dated Dec. 11, 2014 (ECF. No. 54) ("Santoro Supp."); Tr. 332-55.

Dr. Santoro currently works at Atlantic Gastroenterology Associates, P.A. as a doctor of osteopathic medicine and gastroenterology. *See* Ex. 39, dated Aug. 14, 2014 (ECF No. 47) ("Santoro CV"); Tr. at 131. He obtained his Bachelor of Arts in biology from LaSalle College in 1973, and his M.D. from Philadelphia College of Osteopathic Medicine in 1978. Santoro CV at 1. He completed an internship at John F. Kennedy Memorial Hospital from 1978-79, and performed his residency in internal medicine at the University of Medicine and Dentistry at the NJ School of Osteopathic Medicine from 1979-81. *Id.* Dr. Santoro also completed a fellowship in gastroenterology at the University of Medicine and Dentistry NJ School of Osteopathic Medicine from 1981-83. *Id.* at 2. He is board certified in internal medicine and gastroenterology. *Id.* Additionally, he serves as a clinical associate professor of medicine at Rowan University School of Osteopathic Medicine. *Id.* at 3. Dr. Santoro is not a neurologist or an immunologist, and his testimony was focused on Ms. Morgan's diagnosis and onset. Tr. at 348.

Dr. Santoro briefly testified that he agreed with the diagnosis of gastroparesis for Petitioner. Tr. at 338-39. He noted that proper test results revealed delayed emptying of Petitioner's stomach, a finding compatible with gastroparesis, and he relied on the judgment of Dr. Choudhary, an

individual with whom he has professionally interacted and a person he deemed a competent physician. *Id*.

Dr. Santoro went on to maintain that the April 2009 vaccines were the cause of Ms. Morgan's injury, citing (and primarily relying upon) Pande for that conclusion. Tr. at 340, 353. He also cited more recent studies published by Merck indicating a potential association between Gardasil and gastroparesis, although he recognized that Ms. Morgan had not received the Gardasil vaccine. *Id*. at 340-41, 348. Dr. Santoro otherwise avoided testifying about possible causal mechanisms in this case, based upon his express acknowledgment that his primary expertise did not lie in immunology. *Id.* at 352.

In addition, and relying on the affidavits of the Morgans (but without being present for their testimony),[16] Dr. Santoro concluded that the timing of Ms. Morgan's gastroparesis (three days after vaccination) was temporally reasonable. Tr. at 339, 341-42. In so proposing, he dismissed the idea that any viral infection Ms. Morgan experienced in February could have been the trigger for her gastroparesis, deeming a two-month gap from infection to first symptoms too long. *Id*. at 341. He more fundamentally disagreed with Respondent's contention that a minor viral syndrome could constitute a more potent immunogen than the impact of four vaccines received at once. *Id.* at 342. When questioned as to the basis for this belief, Dr. Santoro primarily referenced his personal experience with patients. *Id*. at 350. He also distinguished the minor viral illness Ms. Morgan purportedly experienced with more serious infections such as rheumatic fever, which he allowed could be more powerful than a vaccination. *Id*. at 351.

Dr. Santoro proposed that the improvement of Ms. Morgan's gastroparesis after treatment (in particular, after botox injections) confirmed its neurologic basis (Tr. at 343), in contrast to suggestions by Respondent that it might have had its origin in psychological issues. In his clinical practice, it is quite common for symptoms to improve because the nerves can regenerate, easing gastroparesis symptoms. *Id.* at 343-44. By contrast, had Petitioner's gastroparesis been the result of psychological issues, or reflected a symptom of a larger functional dyspepsia, botox would not have been effective – nor would it even have been proposed. *Id*. at 345-47.

D. *Respondent's Expert – Dr. Randy Longman*

Dr. Randy Longman prepared an expert report and testified at hearing for Respondent. *See* Expert Report, filed as Ex. E, dated March 3, 2016 (ECF No. 63) ("Longman Rep."); Tr. at 156-332. Dr. Longman opined that Ms. Morgan's gastroparesis was either idiopathic or a sequela of her February 2009 viral illness, rather than attributable to vaccination. Longman Rep. at 6. Otherwise, his reports and testimony mainly attempted to rebut various assertions of Drs. Gershwin and Santoro about causation. *See generally* Longman Rep.; Tr. at 161-332.

[16] Dr. Santoro testified remotely, and was not telephonically connected to the courtroom during the Morgans' factual testimony.

Dr. Longman is a gastroenterologist and mucosal immunologist. Ex. F, dated March 3, 2016 (ECF No. 63) ("Longman CV"); Tr. at 156-57; Longman Rep. at 6. He completed his Bachelor of Science degree at Yale University in New Haven, Connecticut, then obtained a dual M.D./Ph.D. from Cornell University. Longman CV at 1. He thereafter completed a gastroenterology fellowship at Columbia University. Tr. at 159, Longman CV at 2. After completing a post-doctoral fellowship in mucosal biology at New York University, Dr. Longman was hired as an assistant professor at Weill Cornell Medicine, where, in addition to teaching, he practices as a gastroenterologist and runs a research lab. Tr. at 159, Longman CV at 1.

In his clinical practice, Dr. Longman's specialty is inflammatory bowel disease, although he also sees patients with immune system hyper-activated intestinal diseases plus a variety of gastrointestinal disorders. Tr. at 157. He estimated that over the years he has seen hundreds of patients with gastroparesis, although it is not a major component of his clinical practice. *Id*. at 158, 227. Dr. Longman's research and publications have been focused on "defining roles for particular types of immune cells and how they integrate the signals from bacteria to regulate mucosal immunity and systemic immunity." *Id*. He is not, however, board certified in immunology or neurology. *Id.* at 220.

Dr. Longman largely accepted Ms. Morgan's gastroparesis diagnosis (although he did propose it could also be understood as a symptom of a more generalized condition). Longman Rep. at 6; Tr. at 164. He questioned, however, two premises of Dr. Gershwin's theory that Ms. Morgan's gastroparesis was autoimmune and mediated by molecular mimicry. First, he maintained that the mechanism of antigen-specific molecular mimicry is *not* consistent with the known pathophysiology of gastroparesis. Tr. at 165. Second, Dr. Longman contended that the immune system would not allow aberrant activation via molecular mimicry, as proposed by Dr. Gershwin, sufficient to cause gastroparesis. *Id*.

To support his first contention, Dr. Longman described what is understood about gastroparesis and how it occurs. Tr. at 167. Dr. Longman defined gastroparesis as delayed gastric emptying, and as a somewhat common finding in gastroenterology, affecting about five million individuals in the United States. Tr. at 172; H.P. Parkman, *et al., Gastroparesis and Functional Dyspepsia*, 22 Neurogastroenterology & Motility 2, 113-33 (2010), filed as Ex. 38, dated Aug. 14, 2014 (ECF No. 47) ("Parkman"). Epidemiologic studies involving gastroparesis have revealed that it is more common in women, suggesting that hormonal imbalances may play a role in developing the condition. Tr. at 176; T. Ali, *et al*., *Gastroparesis*, 100 Southern Med. J. 3, 100 (2007), filed as Ex. 46, dated Sept. 30, 2015 (ECF No. 60) ("Ali"). Dr. Longman did, however, admit that there was an overall paucity of applicable epidemiologic evidence going either way on the issues posed in this case (Tr. at 238-39).

In Dr. Longman's understanding, most cases of gastroparesis are idiopathic with no known causative agent, or can be symptomatic of functional dyspepsia—an umbrella term used for many kinds of gastrointestinal issues. Tr. at 168. In 40 percent of gastroparesis cases, psychiatric comorbidities also exist. E. Saliakellis and M. Fotoulaki, *Gastroparesis in Children*, 26 Annals of Gastroenterology 204-11 (2013), filed as Ex. N, dated Mar. 18, 2016 (ECF No. 64) ("Saliakellis"); Tr. at 178. Gastroparesis is also known to be caused by some over-the-counter medications such as antacids, antihistamines, and opiates. Ali at 3. Finally, Dr. Longman opined that viral infections can cause gastroparesis, particularly rotavirus. Saliakellis at 205; Tr. at 179.

Autoimmune-induced gastroparesis, by contrast, was in Dr. Longman's understanding "essentially unheard of," at least in his personal experience, although he allowed for its exceedingly rare possibility. Tr. at 172, 321. In so asserting, Dr. Longman attempted to provide a medical basis for his view. Wild virus infections, he reasoned, produce gastroparesis via the generalized inflammation they encourage – not by an antigen-specific response in the GI region, as an autoimmune process would be understood to occur. Tr. at 180. Viral inflammation specifically encourages gastroparesis by prompting the release of pro-inflammatory cytokines, which can affect the muscle fibers that comprise gastric muscles. *Id*. at 181. Given its etiology, gastroparesis is reversible – as opposed to what he expected would be the case if it were truly autoimmune in nature. *Id.* at 322.

Besides testifying to the implausibility of autoimmune-mediated gastroparesis, Dr. Longman discussed in his report and testimony his views on whether molecular mimicry could be the mechanism for initiating such autoimmunity. He noted that Dr. Gershwin had not identified homology between any component of the vaccines Ms. Morgan received and a self peptide sequence in the stomach. Tr. at 203. He also took issue with the idea that the mere showing of protein sequence homology between a host tissue and foreign antigen would be enough *in any case* to establish cross-reactivity. *Id.* at 204.

More specifically, Dr. Longman reviewed in detail some of the specific diseases identified by Dr. Gershwin in explaining his theory, in an effort to rebut Petitioner's argument that gastroparesis could be the product of an autoimmune process by establishing that such diseases were "mechanistically different," and therefore undermined, rather than corroborated, Petitioner's theory. Longman Rep. at 3. For example, he noted that gastroparesis can be a "paraneoplasia" – an indirect side effect of cancerous tumors in the body expressing abnormal proteins. Tr. at 194; Longman Rep. at 3-4. In such cases, however, the "antigen is being expressed by the tumor," and thus the tumor *itself* is the direct cause of an immune response that indirectly causes neuronal damage elsewhere in the body; there is no "mimicking" of a self-protein structure, as would be the case under Dr. Gershwin's theory. *Id.* at 195-96.

Dr. Longman similarly took issue with Dr. Gershwin's analogy to Chagas disease, which can cause secondary neuronal damage in the gut. In Dr. Longman's understanding, Chagas disease is not mediated by molecular mimicry in the same sense as Petitioner proposes. Longman Rep. at 4. Rather, Dr. Longman opined, it occurs due to a parasite-borne infection. Tr. at 196. Sustained tissue damage directly caused by the pathogenic infection is what results in the secondary presentation of a neural tissue antigen, making the disease process not at all comparable to what Dr. Gershwin was proposing a vaccine could accomplish. *Id.* at 197.

Dr. Longman also discussed Dr. Gershwin's invocation of instances in which anti-neuronal antibodies are alleged to cause neurologic GI harm. Tr. at 198-201. Citing some of the literature filed by Respondent, he noted that the mere presence of such antibodies does not mean they played a role in a disease's pathogenesis. *Id.* at 198. On the contrary – Dr. Longman opined that the literature better supported the conclusion that the antibodies develop not as "a mechanism of disease" but by happenstance *after* cellular death. *Id.* at 199. In fact, Dr. Longman maintained, such literature established (concurrent with his prior discussion of tumors and direct infections and their secondary effects) that neuronal damage in such instances sufficient to result in gastroparesis was mediated by the inflammation caused by the *primary* insult, with anti-neuronal antibodies actually serving to moderate or inhibit the response rather than propagating it. *Id.* at 200-01. Again, however, it was the direct insult of a more dramatic event that secondarily caused gastroparesis, and not that the gastroparesis was autoimmune-mediated.

The treatments Ms. Morgan received for her gastroparesis, as well as her condition after diagnosis, provided Dr. Longman additional evidence to support his opinion that her condition was not autoimmune in origin. Thus, although botox and erythromycin are common treatments for gastroparesis, plasmapheresis (which Petitioner did *not* receive) is reserved for conditions that are known to be mediated by antibodies because it can filter out antibodies that cause the pathogenesis. *Id*. at 187-88. But Dr. Longman was unaware of anyone in medicine even recommending it as a treatment for gastroparesis. *Id*. at 189. Dr. Longman also pointed out that Ms. Morgan experienced some reversal in her gastric emptying delay after her diagnosis. *Id.* at 213. Such improvement would have been much less likely if Petitioner's theory of autoimmune neuronal damage was correct. *Id*. And he did not see in Petitioner's records evidence that she had ever experienced *any* autoimmune reaction, given the mostly negative test results in the time prior to the scintigraphy test revealing her gastroparesis. *Id.* at 321-22.

Regarding his second contention (that the immune system would not allow such an aberrant activation via molecular mimicry), Dr. Longman focused on the idea that there are multiple levels of checks and balances in the body to prevent an autoimmune reaction. Tr. at 165, 209. He conceded that people *do* experience autoimmune conditions, but in his understanding they occur frequently in the setting of specific genetic mutations allowing for a break in immune tolerance,

rather than from some unspecified and/or unidentified genetic predisposition. *Id*. at 165, 167.[17] If a patient's immune tolerance had been compromised, as Ms. Morgan's experts argued, Dr. Longman would expect to see "systemic antibody productions as well as other manifestations," but the record did not disclose such antibodies having been revealed after testing. *Id*. at 169.

In addition to questioning the autoimmune character of gastroparesis, Dr. Longman challenged the adequacy of proof linking *any* vaccine to the illness, testifying that he could not identify any such evidence on his own. Tr. at 189. He specifically rejected Pande as a reliable source of information establishing a potential association between vaccination and gastroparesis. *Id*. at 181, 190. Rather, he viewed Pande as a collection of a few case reports, characterizing it as "anecdotal" evidence not rising to the level of reliable scientific proof of a causal link. *Id*. at 190-91.[18] On cross-examination, he acknowledged that case studies were not wholly without scientific interest, but insisted that the three case studies in Pande involving vaccines had limited applicability, to the extent they involved post-vaccination presentations that were not comparable temporally to what Ms. Morgan experienced, or three different antigenic deliveries, reducing what could be concluded about the relationship between vaccination and illness in this case. *Id.* at 253.

Dr. Longman's reports and testimony devoted some effort to proposing possible alternative causes for Ms. Morgan's gastroparesis. For example, in his estimation Petitioner's documented February 2009 viral infection could as likely have caused her gastroparesis as the vaccines, deeming the eight-week period that intervened as a reasonable, albeit somewhat long, timeframe for an autoimmune condition (as alleged by Petitioner's theory) to occur. Tr. at 327.[19] In so arguing, however, he noted that not all viral infections posed the same risk for gastroparesis (*Id.* at 256-57), making it less likely she suffered from typical flu infection (*Id.* 261) as opposed to

[17] In so maintaining, Dr. Longman disputed the idea that genetic heterogeneity means that each individual possesses his own distinct "personalized autoimmunity" potentiality. Tr. at 205, 211. He similarly questioned Dr. Gershwin's suggestion that evidence that individuals have different reactions to the flu virus was evidence of such immune system differences, arguing that instead other comorbidities better explained why some individuals might have a worse flu response than others. *Id.* at 207.

[18] Dr. Longman also pointed out that an abstract cited by Dr. Santoro with the same authorship as Pande (H. Pande, M.D. Crowell, *et al., Gastroparesis after Td Vaccine Injection*, 95 Am. J. of Gastroenterology, 2595 (2000), filed as Ex. 36, dated Aug. 14, 2014 (ECF No. 47)) was actually just one of the case studies referenced in Pande itself (which was published some years thereafter as well), and therefore did not constitute additional authority building on Pande's proposals. Tr. at 290-92.

[19] In cross-examining Dr. Longman, Petitioner made a concerted effort to challenge whether evidence about the viral link to gastroparesis was relevant to Ms. Morgan's specific circumstances because she was a child at the time she first experienced symptoms, arguing that the studies suggesting this association were outdated (Tr. at 269), inadequately powered to be reliable (*Id.* at 241-50), or involved samples of adults instead of children. *Id.* at 250-52. Petitioner also attempted to establish that little was actually known about the causes of gastroparesis in children (*Id.* at 262-65), although Dr. Longman observed in response that if this is true, then the adult tests relied upon herein to measure rate of stomach emptying (and therefore the primary diagnostic evidence relied upon by Ms. Morgan's treaters) were of little utility in establishing the accuracy of the diagnosis in the first place. *Id.* at 265-66.

something else if the infection had caused the gastroparesis. *Id.* at 257. But he acknowledged under cross-examination that her subsequent history (characterized by a waning of gastroparesis symptoms while nausea remained), was inconsistent with the conclusion that the illness had a viral source. *Id.* at 285. He also agreed (when confronted with literature discussing possible causes) that viral infections resulting in gastroparesis were less common. *Id.* at 272, 278, S. Waseem, *et al.*, *Spectrum of Gastroparesis in Children*, 55 JPGN 2, 166-72 (Aug. 2012), filed as Ex. 44, dated Sept. 30, 2015 (ECF No. 60) ("Waseem").

Another explanation for Ms. Morgan's gastroparesis proposed by Dr. Longman was that it was merely a symptom of "functional dyspepsia."[20] In support, he stressed the symptom overlap between the two (Tr. at 306-07), and cited literature suggesting that 50 percent of children suffering from functional dyspepsia also experienced delayed gastric emptying, a primary clinical symptom of gastroparesis. *Id.* at 307. He also noted that Ms. Morgan's gastric emptying improved, while other symptoms, such as nausea and abdominal pain, persisted, further supporting the conclusion that functional dyspepsia was the better diagnosis for her condition. *Id.* at 213.

III. Procedural Background

After initiating this action in February 2012, Ms. Morgan began filing medical records in support of her claim, although the process was somewhat lengthy and was not completed for more than a year. Respondent's Rule 4(c) Report was then filed on August 27, 2013 (ECF No. 34), recommending against an award of compensation. Petitioner was thereafter ordered to file an expert report, but did not do so until the following August 2014, with Dr. Santoro's report. ECF No. 47. Respondent filed an expert report (from an expert who did not ultimately testify in this matter[21]) in response on October 14, 2014. ECF No. 52.

I next directed Petitioner to file a supplemental report addressing points raised by Respondent's expert, and she did so (utilizing Dr. Santoro a second time) on December 11, 2014 (ECF No. 54). After reviewing the supplemental report, Respondent expressed the view that dismissal of the case (primarily arguing that there was too great a temporal gap between vaccination and onset of symptoms as reflected in Ms. Morgan's first documented treatment for her gastroparesis) was warranted, and requested an opportunity to so move, which I permitted. *See* Order, dated December 19, 2014 (ECF No. 55). Six months later, after the issue was fully briefed,

[20] Functional dyspepsia has no known cause but usually results from nervousness or anxiety often resembling a peptic ulcer, although an ulcer is not otherwise present. *Dorland's* at 579.

[21] Respondent's initial expert report was authored by Dr. Andrew Warner, a gastroenterologist. Later in the case, when it became clear that the parties did not dispute the gastroparesis diagnosis, and after Ms. Morgan filed Dr. Gershwin's report, Respondent filed the report of Dr. Longman, whose gastroenterology expertise is supplemented by some immunology background. Respondent subsequently determined that there was no need to call Dr. Warner, given the general agreement as to diagnosis, and presented only Dr. Longman.

I denied Respondent's motion. *See* Order, dated June 30, 2015 (ECF No. 58). In so doing, however, I noted there remained a deficiency of proof supporting Petitioner's overall causation theory, and suggested that obtaining more specialized immunologic expertise to support her claim was advisable.

To that end, Petitioner filed an expert report from Dr. Gershwin on September 30, 2015 (ECF No. 59). Respondent expressed an interest in filing an additional report of his own, filing Dr. Longman's expert report on March 3, 2016 (ECF No. 63). By April, the parties agreed upon trial dates for May 2017 and I issued a prehearing order. Order, dated April 6, 2016 (ECF No. 66). The hearing was later bifurcated into two separate dates, to accommodate the needs of fact witnesses and party schedules. *See* Amended Prehearing Order, dated February 6, 2017 (ECF No. 67). The hearing went forward as scheduled, and then the parties were instructed to file simultaneous post-hearing briefs, which were received by early August 2017 after some extensions of time. This matter is now ripe for a decision.

IV. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[22] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not

[22] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[23]

[23] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human*

Servs., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528;

see also Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir.

1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial for a (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 91997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to – and likely undermines – the conclusion that it was not considered").

ANALYSIS

The parties largely accept that Ms. Morgan was properly diagnosed with gastroparesis (although fact issues about its persistence and severity have led Respondent to propose that her condition might be better explained as a symptom of a more generalized dyspepsia), but dispute that the vaccines she received in April 2009 were causal of it. I will review Petitioner's evidentiary showing on each of the relevant *Althen* prongs separately.

I. *Althen Prong One*

There was an overall absence of persuasive scientific evidence in this case associating vaccination with gastroparesis. The sole filed item of literature that came the closest to linking the two was Pande. Both of Petitioner's experts deemed it significant. *See, e.g.*, Tr. at 149 (Dr. Gershwin's testimony), 340 (Dr. Santoro).[24] Dr. Santoro even acknowledged Pande as the primary source for his causation theory, quoting its language directly in his report. *Id.* at 353.

Pande is a 2002 review article written by several gastroenterologists discussing five case-study reports of gastroparesis after vaccination or diagnosed Lyme disease. Pande at 2664. Only three of the five studied patients received a vaccination, and of that sub-set, only one received a vaccine (the Td vaccine) comparable to any vaccines Ms. Morgan received in April 2009. Pande at 2664.[25] In that one most comparable case, a 21-year-old developed gastroparesis, with symptoms presenting three days after vaccination severe enough to require immediate hospitalization. *Id.* Pande's authors opined that the reactions to vaccines could hypothetically be akin to the autoimmune, inflammatory response understood to trigger peripheral neuropathies like Guillain-Barré syndrome ("GBS") or brachial neuritis, bulwarking their proposal with the fact that the

[24] Dr. Santoro's report also included a reference to Pande, filed as Ex. 37.

[25] The other two cases involved the hepatitis B vaccine and anthrax vaccine. Pande at 2664.

studied cases (which included two instances in which individuals developed gastroparesis after experiencing Lyme disease) replicated a post-viral infection-caused gastroparesis given the "abrupt onset," but in the absence of a known pre-vaccination infection. *Id.* at 2666. Pande acknowledged, however, that its hypothesis of an association between gastroparesis and vaccines lacked certain corroborating proof (for example, evidence that individuals re-challenged with the same vaccine became sick again), and that vaccination therefore remained an unestablished cause for the condition. *Id.* at 2664, 2667.

Pande is reliable evidence supporting Petitioner's claim.[26] However, it deserves only limited weight in my analysis, given its foundation - three case studies. *Doe/16 v. Sec'y of Health & Human Servs.*, No. 06-670, 2008 WL 2390064, at *14 (Fed. Cl. Spec. Mstr. June 2, 2008) (citing *Daubert*, 509 U.S. at 594–96 ("[c]ausal attribution based on case studies must be regarded with caution, largely because they lack control and thus do not provide the level of information or detail found in epidemiologic studies")). Pande's age also reduces its probative value. In the 15 years since its publication, its hypotheses have not been tested or confirmed with further research. *Braccio v. Sec'y of Health & Human Servs.*, No. 90-1318V, 1993 WL 59266, at *9 (Fed. Cl. Spec. Mstr. Feb. 19, 1993) (overreliance on outdated medical literature cited as one basis for finding causation was not established). More significantly, only *one* of the Pande case studies involved a vaccine comparable to what Ms. Morgan received, but it is *not* the vaccine that Dr. Gershwin opined was most likely responsible for her alleged reaction (Tr. at 140-41) (opining that the meningococcal vaccine was most likely the cause of Ms. Morgan's gastroparesis).

Beyond Pande, Petitioner's experts offered no proof that *any* vaccine has been associated with gastroparesis. By contrast, the more recent overview articles discussing gastroparesis often cite Pande but do not explicitly or implicitly embrace its suggestions or expand on its hypotheses. *See*,

[26] I am aware of one published decision in which a claimant successfully established entitlement to damages based upon the theory (derived from Pande) that the tetanus vaccine could cause gastroparesis. *See Roper v. Sec'y of Health & Human Servs.*, No. 00-407V, 2005 WL 3597255 (Fed. Cl. Spec. Mstr. Dec. 9, 2005). Of course, I am not bound by the decisions of other special masters (although they can provide persuasive analysis which should be taken seriously when similar cases are presented). Indeed, as noted by the Federal Circuit (albeit in a non-precedential determination), "[a] special master's acceptance of a theory in one case does not require him or her to accept the theory in subsequent cases involving similar facts or the same vaccine. Rather a different evidentiary record can lead to different outcomes." *Rickett v. Sec'y of Health & Human Servs.*, 468 Fed. App'x 952, 959 (Fed. Cir. 2011).

Roper, moreover, is distinguishable – and not just factually (as discussed below). In *Roper*, the petitioner supported her causation theory with a treater opinion from a physician who not only had direct experience with the claimant in that case, but who was a co-author of Pande (at the time only recently published). *Roper*, 2005 WL 3597255, at *5 (petitioner's expert was a specialist in motility disorders like gastroparesis, and also in his practice generally saw "more patients with gastroparesis than all but a small handful of physicians"). These factors rendered his opinion especially credible and persuasive to the special master who decided *Roper*. Here, by contrast, Petitioner relies on experts who did not directly treat her, and who lack demonstrated specialized expertise in gastroparesis sufficient for me to give the same weight to their pronouncements on the condition as occurred in *Roper*. For these reasons (as well as others set forth below pertaining to the timing element of the *Althen* test), I am not persuaded that *Roper* leads to a favorable determination on the first *Althen* prong in this case.

e.g., *Saliakellis* (2013 article); Waseem (2012) at 166 (citing Pande for the proposition that "the literature [on gastroparesis] is limited, with only a few case series and clinical trials, and little in the way of randomized controlled trials"); Ali (2007). Accordingly, Pande alone provides insufficient grounds to carry Petitioner's preponderant burden.

Petitioner has also not established sufficient reliable scientific or medical evidence to support the conclusion that gastroparesis is autoimmune in nature, or could be caused by an autoimmune process. The general articles submitted in this case discussing gastroparesis do not so allow. Waseem at 166 (gastroparesis in children most commonly attributable to viral infection or is deemed idiopathic in origin); Saliakellis at 205. Parkman allows for only the possibility that gastroparesis "might" have an autoimmune nature, but then goes on to characterize as "controversial" the perceived role that infectious agents (for example, rotavirus) have in causing gastroparesis under such circumstances, given the conflicting evidence for how long or often the gastroparesis lasts. Parkman at 116-17; *see also* K. Bielefeldt, *Gastroparesis: Concepts, Controversies, and Challenges*, Scientifica 1-19 (2012), filed as Ex. 32 (ECF No. 47-2), at 5 (speculating that gastroparesis could be immune-mediated, but noting that the "vast majority of patients" with gastroparesis either have diagnosed diabetes, have had GI surgery, or otherwise are believed to have experienced it based on some idiopathic cause). There simply is not enough reliable scientific evidence on the subject to conclude that gastroparesis is "more likely than not" autoimmune in origin.[27]

Expert testimony did not ameliorate this evidentiary deficiency. Petitioner's primary expert offering an immunologic-based opinion, Dr. Gershwin, relied on a discussion of autoimmunity in other contexts, and the capacity of such conditions to cause autonomic damage, to propose that the same was theoretically possible herein. Dr. Longman, by contrast, persuasively established that gastroparesis was *less* likely instigated by an autoimmune response than some more severe, direct process (i.e., a tumor or wild virus infection). Although there is no doubt that Dr. Gershwin's credentials on immunologic topics are superior to those of Dr. Longman, Dr. Gershwin was not persuasive in establishing the proposed theory, or in rooting it in his own experience or knowledge about GI autoimmune injuries or processes. Indeed, his lack of focused expertise on the injury at hand diminishes the weight I afford his opinion – and this deficiency was not made up for by Dr.

[27] It is no response to the above to argue that the rarity of gastroparesis excuses this evidentiary insufficiency. It is well understood in the Vaccine Program that because virtually *any* injury alleged by a petitioner is by definition "rare," a vaccine is not unsafe simply due to the fact it is found to have caused an injury in a particular case. *See, e.g., Bowes v. Sec'y of Health & Human Servs.*, No. 01-481V, 2006 WL 2849816, at *7 (Fed. Cl. Spec. Mstr. Sept. 8, 2006). For this same reason, Respondent cannot *rebut* a claim by arguing that the vaccine is generally considered safe. But there must *still* be sufficient, reliable, preponderant evidence offered to establish Petitioner's theory. Thus, the vast majority of individuals who receive the flu vaccine do *not* experience GBS, but there *is* sufficient reliable evidence associating the flu vaccine with that disease to support causation, given the number of studies and reports not only associating the two but corroborating the autoimmune process believed to be involved – as reflected in the recent amendments to the Vaccine Injury Table. *See, e.g.* 42 C.F.R. § 100.3(a) (2017) (Section XIV of the Vaccine Injury Table amended to add GBS as a Table injury for the flu vaccine).

Santoro, whose opinion was more conclusory, relying more heavily on Pande than his own expertise with gastroparesis.

Petitioner's proposed mechanism[28] was also insufficiently supported by reliable medical or scientific literature. Petitioner's experts could not convincingly propose *what* component of any of the vaccines she received might have mimicked self-structures in the body, what those structures or target antigens would be, or what antibodies would be subsequently created that would initiate autoimmune damage. And, as noted above, they referenced limited reliable scientific or medical studies connecting any vaccine with gastroparesis, and nothing proposing *how* this would occur. At the same time (and consistent with his testimony rebutting the proposal that gastroparesis was likely autoimmune in character), Dr. Longman was successful in casting doubt on the concept that molecular mimicry could *ever* reliably explain how gastroparesis occurs, given his review of diseases known to be connected to the condition and how such diseases are understood to cause it.

Finally, even if gastroparesis could be established *in some circumstances* to have an autoimmune pathogenesis, Petitioner did not persuasively establish a disease course that would progress in any form comparable to what Petitioner actually experienced. There was a lack of reliable evidence explaining how the meningococcal vaccine in particular (as that was the one identified by Dr. Gershwin as most likely causal) would initiate an autoimmune process that would then persist over time but without reaching a severe point close in time to vaccination. Rather, Dr. Gershwin's analysis stopped at pinpointing *when* a post-vaccination autoimmune process would be reasonably expected to begin; his admitted lack of specific experience with gastroparesis made him unable to opine further on the topic. Tr. at 149-151. Dr. Santoro for his part only attempted to fill this evidentiary gap with conclusory statements. *See, e.g.*, Santoro Supp. at 1 ("[s]he first complained of nausea with vomiting on July 13, 2009 [three months after alleged onset]. In this case, it is my feeling that this was a reasonable temporal relationship to her vaccination").

[28] As has been observed in numerous other cases, a claimant is not *obligated* to establish a biologic mechanism to prevail in a Vaccine Program case. *Doe v. Sec'y of Health & Human Servs,* 95 Fed. Cl. 598 (Fed. Cl. Nov. 5, 2010). One can envision many contexts in which a claimant might successfully establish entitlement to a damages award without trying to prove a mechanism -- for example, where direct, reliable evidence of an association existed between the relevant vaccine and injury, even though researchers had yet to identify a mechanism precisely explaining *how* the vaccine initiated the associated pathogenic process.

But the above does not mean that the strength of the evidence offered regarding a mechanism is irrelevant. Claimants in fact often willingly put mechanism into contention, attempting to establish a plausible and reliable mechanism in recognition of the fact that the other evidence regarding causation is weak or incomplete. Where, as here, a claimant affirmatively so opts, I may not only consider the evidence offered, but weigh it in conjunction with my determination as to whether he has met his preponderant standard. *Crutchfield v. Sec'y of Health & Human Servs.,* No. 09-0039V, 2014 WL 1665227, at*13-15 (Fed. Cl. Spec. Mstr. Apr. 7, 2014).

In sum, Petitioner's causation theory was not reliable or persuasive, even though it had some evidentiary support. This is not a "close case" in which an evidentiary tie should be decided in the Petitioner's favor.

II. *Althen Prong Two*

A threshold fact issue presented in this case was whether onset of Ms. Morgan's initial symptoms occurred before her vaccinations (in which case her claim would collapse). There are medical records that support this conclusion, and some of Petitioner's fact witnesses acknowledged that they may have so informed certain treaters. However, sufficient preponderant evidence has been offered by Petitioner to support the contrary conclusion: that her symptoms began in April 2009, several days after receipt of the vaccines at issue. In particular, I found the calendar and diary materials prepared by Mr. Morgan and filed in the case persuasive contemporaneous proof that Ms. Morgan's generalized nausea and GI symptoms began when alleged. I also accept the testimony of the Morgans about their recollection of events, as well as their explanation for why some records might incorrectly propose an earlier onset.

Despite this determination, however, Petitioner has otherwise not demonstrated it to be "more likely than not" that the vaccines she received in April 2009 caused her gastroparesis.[29] Petitioner has alleged these vaccines initiated an autoimmune process. But there is no evidence in that record that would suggest Ms. Morgan was *experiencing* such a process in the two to three months leading up to the more severe symptoms that later resulted in her hospital visits and subsequent gastroparesis diagnosis in the fall of 2009. There are no test results from the April to July time period that could provide circumstantial support for the conclusion that the vaccines might be causing the cross-reaction proposed by Dr. Gershwin.[30] And no treaters ever proposed that the vaccines she had received had anything to do with her injury.

In addition, it has not been established that Ms. Morgan possessed a peculiar or specific genetic makeup that would render her susceptible to an autoimmune reaction. Rather, Petitioner's experts *assumed* that the very fact she experienced a rare injury at all was circumstantial proof of her "unique genetic repertoire." Tr. at 152. This kind of circular logic (the injury is itself proof of causation) does not meet the preponderant evidentiary standard set for a vaccine injury claim.

[29] Of course, having already concluded that preponderant evidence does not support Petitioner's causation theory, I need not consider whether she has satisfied the "did cause" prong of the *Althen* test. *See, e.g., Lasnetski v. Sec'y of Health & Human Servs.*, 128 Fed. Cl. 242, 64 (2016) (not error for special master to forego *Althen* analysis after determining that a petitioner had not in fact experienced the disease or illness alleged to have been vaccine-caused), *citing Hibbard*, 698 F.3d at 1365. I nevertheless review briefly the deficiencies in this aspect of Petitioner's case.

[30] Dr. Gershwin's point that Ms. Morgan's treaters did not think to look for evidence of autoimmunity initially as an explanation for the absence of such evidence has some merit – but it could equally be understood to weaken the argument that Ms. Morgan's symptoms were likely autoimmune (since those same treaters did not interpret her symptoms to *require* testing for autoimmunity in the first place).

Dodd v. Sec'y of Health & Human Servs., No. 09-585, 2013 WL 3233210 (Fed. Cl. Spec. Mstr. June 5, 2013), *mot. for rev. den'd,* 114 Fed. Cl. 43, 56 (Fed. Cl. Dec. 19, 2013) (finding no error in the special master's determination that Petitioner's expert use of circular logic was a basis for finding his opinion unpersuasive).

Another case involving vaccination and gastroparesis, *Roper v. Sec'y of Health & Human Servs.*, 2005 WL 3597255 (Fed. Cl. Spec. Mstr. Dec. 9, 2005), illustrates the sort of factual circumstances that would better support the second *Althen* prong under Petitioner's theory – but are absent herein. Four days after receiving the tetanus vaccine, the *Roper* petitioner developed not just nausea, but vomiting and a feeling of fullness, with symptoms progressing to a level of severity within less than a month, resulting in her hospitalization. *Roper*, 2005 WL 3597255, at *2. In addition, contemporaneous medical records revealed that the *Roper* claimant's treaters had openly speculated that her vaccination likely had something to do with her condition. *Id.* And her causation theory was supported by one of these *same* treaters, who had demonstrated specialized expertise in the study and treatment of gastroparesis (and who was also a Pande co-author). *Id.* at *5.

This case tells a different story. I have found that the evidence supports the conclusion that Ms. Morgan's nausea began within a week of the April 2009 vaccines. But she subsequently experienced a more meandering and milder course of symptoms over a three-month period, inconsistent with what Pande suggests would occur.[31] She was ultimately diagnosed with gastroparesis only in the fall of that same year (almost six months after the vaccinations), in far contrast to the *Roper* petitioner. The record also reveals no contemporaneous treater support for the vaccines' purported role, and the overall course of her symptoms has not been shown to be consistent with any of the (limited) medical or scientific evidence offered in this case suggesting gastroparesis could sometimes be autoimmune.

Petitioner also relies heavily on the temporal relationship between her vaccinations and the beginning of her symptoms not long thereafter, along with the overall absence of other identifiable explanations for her later-diagnosed gastroparesis.[32] But this kind of showing has long been understood in the Vaccine Program to be inadequate (especially, as is the case here, where

[31] While I do not find that Respondent successfully established that Ms. Morgan's gastroparesis is better understood as a symptom of general dyspepsia, I was persuaded by Dr. Longman's view, based on his review of the medical record, that her course was on the milder end of the spectrum – further diminishing the likelihood that it reflected an immediate vaccine reaction (as the strongest evidence offered by Petitioner in favor of her theory suggested that onset would become acute fairly rapidly – *not* that an individual would experience symptoms in a milder course).

[32] Respondent attempted to propose explanations for Ms. Morgan's illness – that it was caused by a preexisting infection, or that it was actually just a symptom of generalized dyspepsia. I do not find that the record was sufficiently clear to deem either alternative explanation sufficient. But because Petitioner did not otherwise successfully establish her vaccines as the "more likely than not" cause of her gastroparesis, I find that the record best supports the conclusion that its cause was idiopathic.

Petitioner's *Althen* one showing is deficient). *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("a proximate temporal association alone does not suffice to show a causal link between the vaccination and injury"). Without offering some corroborative circumstantial proof establishing that the autoimmune reaction Petitioner is alleged to have experienced was occurring, I cannot conclude that the vaccine injured her simply because she became ill temporally after the vaccines were administered.

III. *Althen Prong Three*

As noted above, I find persuasive Petitioner's assertion that her symptoms began several days after her vaccinations, rather than before. Such an onset is consistent with Petitioner's causation theory regarding when the allegedly autoimmune reaction culminating in her gastroparesis would be expected to begin. But *in this case* Petitioner's causation theory is not sufficiently supported with preponderant evidence. Accordingly, the consistency of the onset timing in this case with Petitioner's theory does not aid Petitioner, when that same theory has been found to lack reliability.

Moreover, even if I had agreed with Petitioner that gastroparesis could be autoimmune in character, the overall temporal course of Petitioner's illness as evidenced by the medical record is inconsistent with that theory as presented in this case, and therefore has not been shown to be "medically acceptable." Pande offers the best evidence associating vaccination with gastroparesis, but it supports a far shorter course for the disease (in which onset is followed almost immediately by severe progression of symptoms). Pande at 3 (gastroparesis symptoms severe enough to require hospitalization began three days after vaccination). The *Roper* case involved a similar progression, with symptoms becoming severe within a month of vaccination. *Roper*, 2005 WL 3597255, at *2. Ms. Morgan's symptoms, by contrast, did not progress to a more severe level until more than three months later (at best), and the delayed gastric emptying that was the strongest evidentiary point favoring the gastroparesis diagnosis was (in Dr. Longman's unrebutted view) fairly mild, given its reversibility. Tr. at 322-23. Thus, the third *Althen* prong is also unsatisfied.

CONCLUSION

It was a pleasure to meet Ms. Morgan and her parents, despite the circumstances of this case, which undoubtedly have been extremely trying for the Morgan family. I have great respect for the loving and attentive care they have provided her, and sympathy as well for their ardent struggle to understand the cause of her suffering, and to provide her the treatment she requires to live in a manner even close to what she knew before her illness. But a Program entitlement award for a non-Table claim must be supported by a preponderant evidentiary showing of causation. Here, Petitioner has not made such a showing. Her proposed causation theory lacks sufficient scientific and medical reliability, and the medical records do not corroborate it. Instead, she relies too heavily

on the temporal association between vaccination and injury, which is not sufficient to prevail. Petitioner is therefore not entitled to compensation under the Vaccine Program.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accord with this decision.

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master